

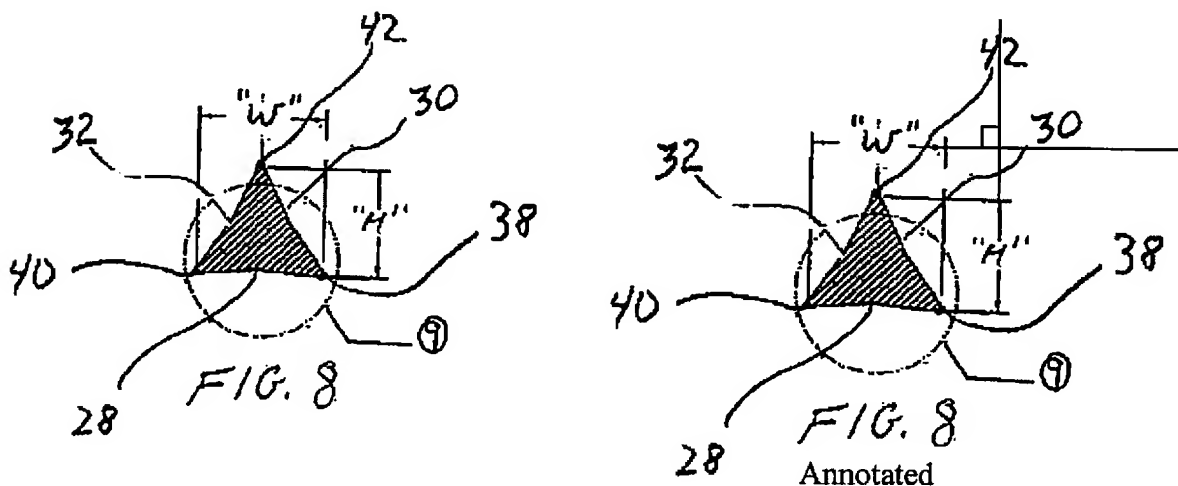
REMARKS

The above referenced application has been reviewed in light of the Final Office Action mailed March 15, 2010. Claims 1-9, 12, 14, 15, 20-22, 24 and 25 are currently pending in this application with claims 1 and 12 being in independent form. No amendments have been made to the claims herein. In view of the remarks to follow, reconsideration and allowance of this application are respectfully requested.

Claims 1-9, 12, 14, 15, and 20-22, 24, and 25 were rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Office Action states that “the applicant has clarified the z-dimension and x-dimension in the independent claims, however at no point are ‘xt’ or ‘zt’ 90 degrees offset from each other (see current application’s Fig. 3 and Fig. 8), and there are three cutting edges that appear to be offset 120 degrees from each other.”

As previously discussed and acknowledged by the Examiner, the z-dimension relates to the width “w” and the x-dimension relates to the height “H” of the surgical needle. Thus, “z_i” extends along the width of the surgical needle and “x_i” extends along the height of the surgical needle. The height and width dimensions are perpendicular to each other and thus offset 90°.

The 90° angle between the x-dimension and the z-dimension is shown in FIG. 8, reproduced below. For further clarification, Applicants have also annotated FIG. 8 by extending the planes of the height and width dimensions until they intersect to show the 90° angle.

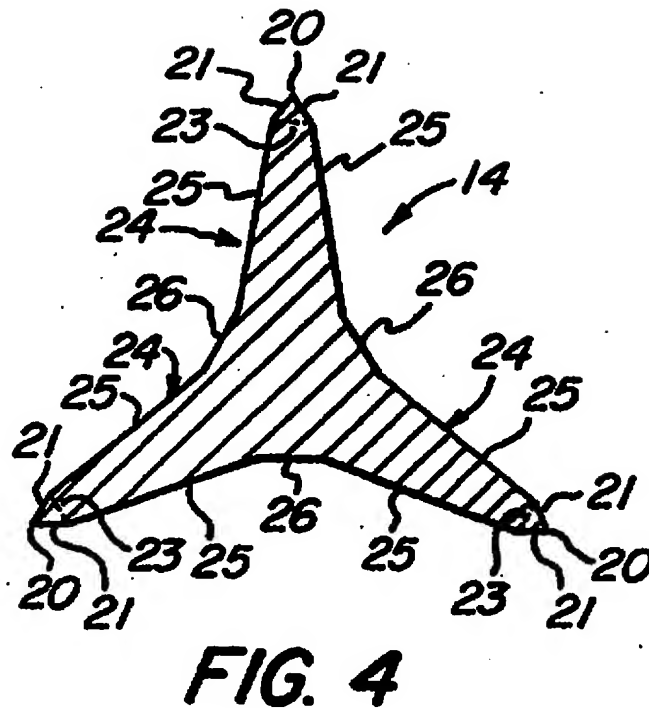


The degree to which the three cutting edges are offset is of no consequence to the present relationship between the width and height dimensions as the spacing of the cutting edges, as shown above, is relative to the longitudinal axis of the needle and not to x- and z-axes.

In view of the foregoing, it is respectfully submitted that the rejection under 35 U.S.C. §112, first paragraph, of claims 1 and 12, as well as claims 2-9, 22, and 24 which depend from claim 1, and claims 14, 15, 20, 21, and 25 which depend from claim 12, has been overcome and should be withdrawn.

Claims 1-9, 12, 14, 15, 20-22, 24, and 25 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,403,344 to Allen in view of U.S. Patent No. 4,565,545 to Suzuki. Applicants respectfully submit that Allen and Suzuki, either alone or in combination, fail to teach or suggest the claimed surgical needle and that there is no reason, motivation, or suggestion in Allen or Suzuki to combine the references.

With initial regard to Claim 1, and in contrast to the limitations of Claim 1, Allen does not disclose a “needled end portion having three sides which intersect to define three cutting edges and terminate at a needle point, each side including *one sole pair of planar surface portions* arranged in oblique relation to define a general concave appearance to each side” (emphasis added). In the Office Action, the Examiner relies on FIG. 4 of Allen to support the assertion that Allen discloses this feature. Inclusive of FIG. 4 of Allen, reproduced below, it is clear that Allen does not disclose a “needled end portion having three sides which intersect to define three cutting edges and terminate at a needle point, each side including *one sole pair of planar surface portions*,” as required by Claim 1. In particular, each side of Allen’s needle include *five* planar surface portions, i.e., reference numbers 21, 21, 25, 25, and 26. Suzuki also fails to disclose this feature. For at least this reason Claim 1, and its dependent claims, are allowable under 35 U.S.C. §103(a) over Allen and Suzuki.

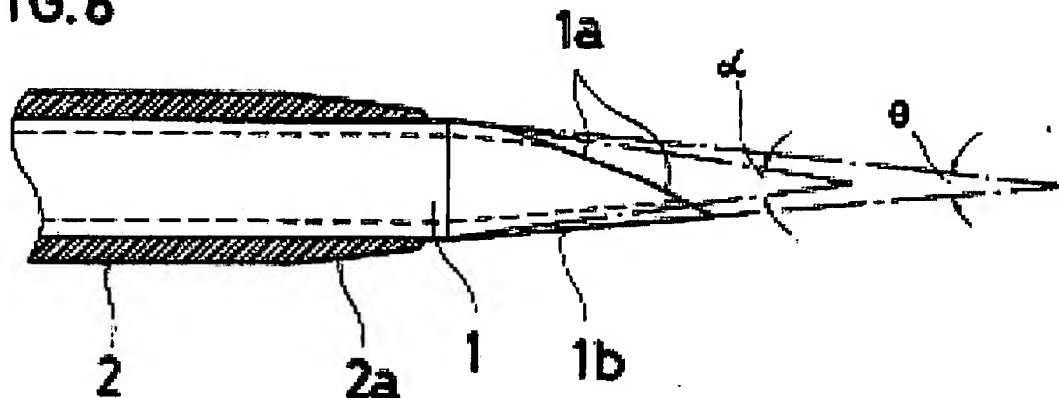


With regard to Claim 12, independent Claim 12 requires a surgical needle comprising, *inter alia*, “each side including a pair of planar surface portions arranged in oblique relation and intersecting along a median plane bisecting a respective side.” This feature is shown in FIG. 8 of Applicants’ disclosure, reproduced above. In the Office Action, it was not asserted which reference discloses this feature. As shown with reference to FIG. 4 above, Allen fails to disclose this feature including a pair of planar surface portions that intersect along a median plane that bisects a respective side. Suzuki also fails to disclose this feature. For at least this reason Claim 12, and its dependent claims, are allowable under 35 U.S.C. §103(a) over Allen and Suzuki.

Moreover, as acknowledged by the Examiner, Allen fails to teach or suggest a surgical needle including, *inter alia*, a “needle point being displaced a predetermined distance with respect to the longitudinal axis and wherein the predetermined distance is less than $\frac{1}{2}$ the x-dimension ‘ x_t ’ of the enlarged transition portion, and at least one side of the needled end portion being displaced by an angle α from a plane parallel to the longitudinal axis, the angle α being between about 2° and about 10° , wherein the side of the needled end portion displaced by angle α from the plane parallel to the longitudinal axis has a substantially continuous slope between the enlarged transition portion and the needle point,” as required by both independent claims 1 and 12.

Suzuki fails to cure the deficiencies of Allen. Suzuki discloses a catheter insertion device used for percutaneous insertion of a catheter into an artery or a vein located in a deep part of a tissue. As illustrated in FIG. 8, reproduced below, the catheter insertion device includes an inner needle 1 including a taper portion 1b and a beveled surface 1a at its distal end. According to Suzuki “it is possible to decrease the size of the incision in the tissue because it is formed by the beveled surface of the tapered needle point with a smaller diameter, and the desired objects can be accomplished by means of an elastic insertion of the catheter into the smaller incision.” (See Abstract of Suzuki.)

FIG. 8



Suzuki fails to disclose “at least one side of the needled end portion being displaced by an angle α from a plane parallel to the longitudinal axis, the angle α being between about 2° and about 10° , wherein the side of the needled end portion displaced by angle α from the plane parallel to the longitudinal axis has a substantially continuous slope between the enlarged transition portion and the needle point.”

In the Office Action, it was asserted that Suzuki discloses angle alpha as “being between about 2° and 10° (col. 4, ll. 47, alpha is derived using theta).” The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. Thus, to the extent the Examiner contends that the angle of displacement of one side of the needled end portion from a plane parallel to the longitudinal axis can be derived from angle theta, the Examiner is respectfully requested to specifically point out the value of angle alpha.

Additionally, assuming *arguendo* that all of the limitations of the Applicants’ claims are taught by the combination of Allen and Suzuki, which they are not, the combination of the surgical needle of Allen and the cannula insertion device of Suzuki is improper. Allen is directed to a surgical suturing needle including a needle head that is shaped so that the only

portion that substantially contacts tissue during cutting is the three cutting edges to improve penetration performance, lessen tissue trauma and distortion, and reduce the wound opening area. (See, Allen at col. 3, lines 48-60). That is, a major purpose of Allen is to minimize the surface area of the needle that contacts tissue.

Suzuki, on the other hand, is directed to a catheter insertion device including an inner needle and an outer catheter capable of forming an incision in a blood vessel that is smaller than the outside diameter of the inner needle by utilizing a beveled and tapered needle end.

In the Office Action, it was asserted that “it would have been obvious to one of ordinary skill in the art to use the geometry of Suzuki with the device of Allen, as the angle blade *increases the surface area* of the blade and aids in cutting the tissue” (emphasis added). However, as stated above, the needle head of Allen is shaped so that the only portion that substantially contacts tissue during cutting is the three cutting edges. It is this feature that provides the needle of Allen with its improved characteristics as also described above. Thus, increasing the surface area of Allen’s needle, as suggested by the Examiner, is contrary to the teachings of Allen and would change the principle of operation of Allen.

According to §2143.01(VI) of the MPEP, the proposed modification cannot change the principle of operation of a reference -- “If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.”

Accordingly, in view of the foregoing remarks/arguments, Applicants respectfully submit that the rejections of claims 1 and 12, as being unpatentable under 35 U.S.C. §103(a) over Allen in view of Suzuki has been overcome.

Since claims 2-9, 22, and 24, which depend from claim 1, and claims 14, 15, 20, 21, and 25, which depend from claim 12, contain all of the limitations of claims 1 and 12, respectively, for at least the reasons presented above regarding the patentability of claims 1 and 12, Applicants respectfully submit that each of claims 2-9, 14, 15, 20-22, 24, and 25 is also patentable over Allen and Suzuki.

As a final matter, the Office Action states that "Applicant's amendment necessitated the new ground(s) of rejection presented in this Office Action. Accordingly, THIS ACTION IS MADE FINAL." (Page 6 of the Final Office Action dated March 15, 2010). Applicants respectfully disagree with the finality of the Office Action. The amendments to the previous office action were in response to various §112 rejections to differentiate between the x-dimensions " x_i " and " x_1 " and to delete a wherein clause. No amendments were presented which necessitated the new ground(s) of rejection. Therefore, Applicants respectfully request withdrawal of the finality of the office action.

In view of the foregoing remarks, Applicants submit that all of the claims are patentably distinct from the references of record and are in condition for allowance. The Examiner is invited to contact the undersigned Attorney at the telephone number listed below with any questions concerning this application.

Appl. No. 10/618,990
Amdt. Dated May 17, 2010
Reply to Office Action mailed on March 15, 2010

Please charge any deficiency as well as any other fee(s) that may become due under 37 C.F.R. § 1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s), to Deposit Account No. 21-0550.

Respectfully submitted,



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